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EXAMINER	
BRUTUS, JOEL F	

ART UNIT	PAPER NUMBER
3768	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/543,001	SARDAR ET AL.	
	Examiner	Art Unit	
	JOEL F. BRUTUS	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21,23-35,37,39 and 42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21, 23-35, 37, 39 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-5, 6-14, 15-19, and 23-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dreher et al (US Pat: 5,303,709) in view of Hay et al (US Pat: 5,632,282) and further in view of Glaser et al (US Pat: 5,767,079) and/or Larrick et al (US Pat: 5,670,151).

Regarding claims 1-5, 7-13, 15-19, and 23-34, Dreher et al teaches means and method for determining thickness of the nerve fiber layer of the fundus of the eye by measuring the polarization shift of the reflected probing light that is pertinent to the claimed invention. Dreher et al further teaches an array of polarizers, a micro computer, a diagnostic beam, corneal polarization compensator, beam splitter, ADC [see fig 3]; the system uses a laser diode to provide a beam of light that is focus by a lens [see column 4 lines 40-44]; a linear polarizer, a laser, laser diagnostic beam, array of polarizers, computer [see column 6 lines 30-50]; a polarization sensitive detection means [see column 2 lines 60-64]; measuring polarization shift [see column 4 lines 33- 40]. Dreher et al also teaches an ellipsometer to capture and analyze polarization information [see

column 6 lines 6-9]; incident diagnostic beam could be scanned by a scanning unit [see column 6 lines 65- 68]; choroid (or choroidal tissue) [see column 3 lines 55-56]

Dreher et al further discloses the technique used to diagnose diseases of the eye. The retinal nerve fiber layer comprises an array of radially arranged nerve fibers. This array acts as a linear birefringent medium. It is illuminated with linearly polarized light, and the reflected from the ocular fundus is passed through an analyzer [see column 8 lines 16-17] with an orthogonal polarized filter to a photo detector or collector [see column 8 lines 17-19]. There will darkness along the polarization axes of both the incident light beam and the analyzer filter. The bright portion of the cross gives an accurate indication of the thickness of the nerve fiber layer at these points as substantial change in the polarization caused by substantial nerve fiber layer thickness will shift the polarization of the light adequately to pass through the analyzer polarization filter [see column 8 lines 20-31].

Dreher et al teach a second photo detector is used to measure the total amount of reflected intensity of the return diagnostic beam at the corresponding points on the fundus. By normalizing the intensity values obtained with the first photo detector with the corresponding values of the second detector, absolute changes in the state of polarization of the return diagnostic beam are calculated [see column 8 lines 43-50]; the polarization technique disclosed make a substantial contribution to the ability to diagnose the interior eye, especially early diagnosis of glaucoma [see column 8 lines 60-63]; a detector that measures absolute intensity of returned diagnostic beam [see column 7 lines 65-67, column 8 lines 1-5] so fig 2 shows two different light beams (32

and 45) that can be referred to as first and second beams and the second detector as taught would be able to detect the maximum intensity of the second light beam (emphasis added); diagnose early glaucoma and eye diseases [see column 8 lines 60-63], a variable retarder to adjust to maximize the intensity of the light in the polarized state [see column 5 lines 50-53].

Dreher et al doesn't teach a tissue sample holder and don't mention neovascularization.

However, Dreher et al teach ocular fundus which is pertinent to the neovascularization according to the description of Glaser et al below.

However, Glaser et al teaches method for treating ophthalmic disorders like retinal disorders, choroidal tissue, macular degeneration, neovascularization, diabetic retinopathy [see column 1 lines 33-36]. Glaser et al disclose that neovascularization is a serious complication of a large variety of ocular disorders affecting the various tissues of the eye because it can lead to blindness. Corneal neovascularization occurs in many conditions and diseases, including trauma, chemical burns and corneal transplantation [see column 5 lines 39-43].

However, Hay et al teaches a method for diagnosing a plurality of disorders of optical media of the eyes is disclosed. A beam light is directed into eyes of a subject, and the retinal reflection, or reflex, emerging from the pupil is detected and analyzed [see abstract]. In some instances intensity levels of the reflex are compared against a reference reflex representative of normal eye to isolate abnormal ocular conditions [see abstract]. Hay et al teaches a device to detect ocular diseases, macular disease such

as degenerative conditions, infection and tumors (cancer) [see column 6 lines 42-50]; the device comprises a chinrest to position the eye within the area of the beam light [see column 8 lines 18-24] and stabilizing bar to stabilize the head and thus the eye [see column 8 lines 22-24].

However, Larrick et al teaches a form of disorder of the eye is diabetes retinopathy [see column 2 lines 13-20].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine the Dreher et al, Hay et al references by using a sample holder as taught by Hay et al; to stabilize the desired examined are as to precisely and accurately focus the laser beam into the eye. An artisan would have been motivated to combine the Dreher et al reference with Glaser et al; for the purpose of providing diagnosis to evaluate the extent or spread of the disease as to prescribe the best possible treatment; thus prevent any further eye problems or blindness.

Regarding claims 6 and 14, all other limitations are taught as set forth by the above combination.

Larrick et al teaches a form of disorder of the eye is diabetes retinopathy [see column 2 lines 13-20].

Glaser et al further teach neovascularization of the iris, and its attendant scarring can result in glaucoma and blindness. Neovascularization of this portion of the eye can arise as a consequence of diabetic retinopathy, venous occlusion, ocular tumors and retinal detachment. Most commonly, laser treatment to cauterize the blood vessels is

tried; however, that has the attendant risk of causing additional scarring. (50) Retinal and intravitreal neovascularization occurs in a wide range of disorders including diabetic retinopathy, vein occlusions, sickle cell retinopathy, retinopathy of prematurity, retinal detachment, ocular ischemia and trauma. (51) Subretinal pigment epithelial (RPE) and sub-retinal neovascularization are common, yet very severe, disorders of the eye. The growth of new blood vessels interferes with the normal anatomy of the visual and pigmentary cells in the eye, leading to severe visual loss. The new blood vessels leak fluid and blood under the macula causing marked distortion and loss of vision. When these blood vessels develop in the avascular foveal region of the eye, the result is central visual loss and legal blindness [see column 5 lines 62-67 and column 6 lines 1-13].

3. Claims 20-21, 35, 37, 39 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dreher et al (US Pat: 5,303,709) in view of Hay et al (US Pat: 5,632,282) as applied to claim 1 above, and further in view of Trachtman (US Pat: 5,002,384).

Regarding claims 20-21, 35, 37, 39 and 42, all other limitations are taught as set forth by the above combination.

The above combination doesn't teach photodiode, digital meter.

However, Trachtman teaches an apparatus for monitoring and training eye position under clinical conditions. Sensors means can be photodiodes [see column 16

lines 41-56]; digital meter [see column 19 lines 25-35, 45-55]; a small computer [see column 19 lines 54-55]; sample holder [see column 19 lines 8-20].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine the Dreher et al, Hay et al and Trachtman references; for the purpose of having the capability of converting light into either current or voltage, depending upon the mode of operation; and using the digital meter for higher accuracy, efficacy and greater precision.

Response to Arguments

4. Applicant's arguments with respect to claims 1-21, 23-35, 37, 39, and 42 have been considered but are moot in view of the new ground(s) of rejection.

The abstraction objection is moot due to the amendment.

Applicant argues that Dreher et al don't teach a disease that involves neovascularization.

However, Glaser et al disclose that neovascularization is a serious complication of a large variety of ocular disorders affecting the various tissues of the eye because it can lead to blindness. Corneal neovascularization occurs in many conditions and diseases, including trauma, chemical burns and corneal transplantation [see column 5 lines 39-43]. And Dreher teaches systems and method of diagnosing ocular fundus; the retinal nerve fiber layer comprises an array of radially arranged nerve fibers. This array acts as a linear birefringent medium. It is illuminated with linearly polarized light, and the reflected from the ocular fundus is passed through an analyzer [see column 8 lines 16-

17] with an orthogonal polarized filter to a photo detector or collector [see column 8 lines 17-19].

Glaser et al further teach neovascularization of the iris, and its attendant scarring can result in glaucoma and blindness. Neovascularization of this portion of the eye can arise as a consequence of diabetic retinopathy, venous occlusion, ocular tumors and retinal detachment. Most commonly, laser treatment to cauterize the blood vessels is tried; however, that has the attendant risk of causing additional scarring. (50) Retinal and intravitreal neovascularization occurs in a wide range of disorders including diabetic retinopathy, vein occlusions, sickle cell retinopathy, retinopathy of prematurity, retinal detachment, ocular ischemia and trauma. (51) Subretinal pigment epithelial (RPE) and sub-retinal neovascularization are common, yet very severe, disorders of the eye. The growth of new blood vessels interferes with the normal anatomy of the visual and pigmentary cells in the eye, leading to severe visual loss. The new blood vessels leak fluid and blood under the macula causing marked distortion and loss of vision. When these blood vessels develop in the avascular foveal region of the eye, the result is central visual loss and legal blindness [see column 5 lines 62-67 and column 6 lines 1-13].

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL F. BRUTUS whose telephone number is (571)270-3847. The examiner can normally be reached on Mon-Fri 7:30 AM to 5:00 PM (Off alternative Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F. B./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768